

Tab 19 PREMARKET NOTIFICATION 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

Manufacturer:

SonoScape Company Limited

Address: 4/F., Yizhe Building, Yuquan Road, Nanshan, Shenzhen 518051,

P.R.China

Tel: (86) 755-26722890

Fax: (86) 755-26722850

Contact Person: Chen Zhiqiang

Date Prepared: July 12, 2011

Name of the device:

* Trade/Proprietary Name:

S8 Diagnostic Ultrasound System

* Common Name: Diagnostic Ultrasound System and Transducers

* Classification:

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Legally Marketed Predicate Device:

K092922, SonoScape S8 Diagnostic Ultrasound System

Device Description:

The SonoScape S8 Ultrasound System, previously cleared under K092922, is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The only modifications that were made are:

The original S8 Diagnostic Ultrasound System, was previously cleared in K092922 dated March 12, 2009, uses an internal SMPS as its power supply system. And the proposed device was redesigned, changing from AC to battery power, i.e. the internal Li-ion Battery Pack (with an external AC adapter). Such a change is accompanied by labeling changes, but not including new indication for use (See Tab 3).

Table 21.1 lists the differences between the two power supply systems.

Table 21.1 Comparison of the Switching Mode Power Supply (SMPS) System and the Battery Pack Power Supply System

Model Item	S8 K092922 (with SMPS)	S8 TBD (with Battery Pack and AC Adapter)
Power supply	No battery pack is provided; The SMPS forms the power supply system.	An internal battery pack is provided; The power supply system consists of the AC adapter and DC converter and a Li-ion Battery Pack.
Working Principle of the Power Supply	The SMPS converts the 220V or 110V mains voltage to the DC voltages (+12V, -12V, +5V, +3.3V, +5VSB) required by all the electronic parts in the S8 Series System.	The AC adapter converts the mains voltage (100-240V AC) to a DC voltage of approximately +17.5V. Supplied with this DC voltage, the DC converter charges the battery and also converts the DC voltage to the lower voltages (+12V, -12V, +5V, +3.3V, +5VSB) required by all the electronic parts in the S8 system, and at the same time controls the LED indicators on the control panel/keyboard.

Model Item	\$8 K092922 (with SMPS)	S8 TBD (with Battery Pack and AC Adapter)
Control Panel/ Keyboard		Compared to control panel of the original certified product, three LEDs have been added at the bottom right corner of the control panel.
Remarks	requires the mains supply to provided, the system can no	k, the S8 System can operate even

Intended Use:

The SonoScape S8 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, OB/Gyn and Urology. This is the **same intended use** as previously cleared for the SonoScape S8 Diagnostic Ultrasound System, K092922.

Probe Information:

Tab 21.2 Probe information

No.	Probe	Туре	Frequency Range	Intended Use
1	2P1	Phased Array	2.0-4.0 MHz	Abdominal
		_		Neonatal Cephalic
				Adult Cephalic
				Cardiac Adult
				Cardiac Pediatric
2	5P1	Phased Array	3.0-7.0 MHz	Pediatric
				Neonatal Cephalic
				Cardiac Pediatric
3	6V1	Micro-curved	4.0-8.0 MHz	Trans-rectal
		Array		Trans-vaginal
4	6V3	Micro-curved	5.0-9.0 MHz	Trans-rectal
		Аггау		Trans-vaginal
5	EC9-5	Micro-curved	5.0-9.0 MHz	Trans-rectal
		Array		Trans-vaginal
6	C611	Micro-curved	4.0-8.0 MHz	Abdominal
		Array		Pediatric
				Neonatal Cephalic
				Cardiac Pediatric

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	No.	Probe	Туре	Frequency Range	Intended Use					
	7	C344	Curved Array	2.0-5.0 MHz Fetal / Abdominal/ Ob/GYN						
	8	C362	Curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN					
	9	VC6-2	Curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN					
	10	L741	Linear Array	5.0-10.0 MHz	Small Organ (reast, thyroid,					
					testes)					
					Musculo-skeletal (Conventional)					
					Peripheral vessel					
	11	L742	Linear Array	5.0-12.0 MHz	Small Organ (reast, thyroid,					
					testes)					
					Musculo-skeletal (Conventional)					
					Musculo-skeletal (Superficial)					
					Peripheral vessel					
	12	L743	Linear Array .	5.0-10.0 MHz	Small Organ (reast, thyroid,					
					testes)					
					Musculo-skeletal (Conventional)					
					Musculo-skeletal (Superficial)					
					Peripheral vessel					

Safety Considerations:

The S8 Diagnostic Ultrasound System incorporates the same fundamental technology as the predicate device. The device has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 9, 2008. The acoustic output is measured and calculated per NEMA UD 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5 and ISO 10993-10.

Testing:

Laboratory testing was conducted to verify that the S8 Diagnostic Ultrasound System met all design specification and was substantially equivalent to the currently marketed Predicate Device as above. The device has been found to

conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. Acoustic output is measured and calculated according to "Acoustic Output Measuring Standard for Diagnostic Ultrasound Equipment".

Tab 21.3 Applicable Safety Standards

Standards No.	Standards Title	Version	. Date
IEC 60601-1	IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.	1988	10/31/2005
IEC 60601-1-2	IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility — Requirements and Tests.	2007	07/31/2008
IEC 60601-2-37	IEC 60601-2-37 (2004) (2005) Amendment 2, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.	2007	09/08/2009
NEMA UD 2	NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.	2004	09/08/2009
ISO 10993-5	ISO 10993-5:1999, Biological evaluation of medical devices Part 5: Tests for In Vitro cytotoxicity.	2009	09/12/2007
10993-10	ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.	2002	09/12/2007

Conclusion:

The conclusions drawn from testing of the S8 Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

SonoScape Company Limited % Ms. Diana Hong General Manager Mid-Link Consulting Co., Ltd P.O. Box 237-023 Shanghai, 200237 CHINA

SEP 16 Tull

Re: K112451

Trade/Device Name: \$8 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: August 24, 2011 Received: August 25, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the S8 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P1 Phase Array	EC9-5 Micro-curved Array	VC6-2 Curved Array
5P1 Phase Array	C611 Micro-curved Array	L743 Linear Array
6V1 Micro-curved Array	C362 Curved Array	L741 Linear Array
6V3 Micro-curved Array	C344 Curved Array	L742 Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safetv/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy, Ph.D. at (301) 796-6242.

Sincerely Yours,

Mary S. Pastel, Sc.D.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

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Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

Tab 3 Indications For Use

510	(k)	Nu	mb	er:

Device Name: S8 Diagnostic Ultrasound System

Indications for Use:

The SonoScape S8 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, OB/Gyn and Urology.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) Number

System:

Sonoscape S8

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	ical Application	T -				Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CMD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
Other	Abdominal	Р	Р	Р		P	P	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	Р	P	Р		P	P	Note 1	Notes 2,4
	Small Organ (specify)	P	P	Р		Р	Р	Note 1	Notes 2,4,6
	Neonatal Cephalic	P	Р	Р	Р	Р	P	Note 1	Notes 24
	Adult Cephalic	P	P	Р	Р	P	Р	Note 1	Notes 2, 4
	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2
	Trans-vaginal	P	Р	Р		P	Р	Note 1	Notes 2
	Trans-urethral		1						
	Trans-esoph.(non-Card)					i			
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	P	Р	Р		Р	P	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult	Р	Р	Р	Р	Р	Р .	Note 1	Notes 2,3
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph (Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2
Vessel	Other (specify)								

	Care (Specify)			į					
Peripheral	Peripheral vessel	P	P	Р		Р	P	Note 1	Notes 2
Vessel	Other (specify)								
N = new indication	n; P = pre	viously	cleare	d by FDA	;		E	= added under th	is appendix
Note 1: Other O	Combined includes: B/M; I	3/PWD	; B/I	HI; M/C	olor M;	B/Color	Doppler; B/Color De	oppler/PWD; E	3/Power
Dopp	oler/PWD								
Note 2: Tissue	Harmonic Imaging.								
Note 3: TDI	Note 4: 3D		No	ote 5: 4D					
Note 6: Small (Organ: breast, thyroid, teste	es							
Prescription Us	se X			AND/C)R		Over-The-	Counter Use	
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Indications For Use

(Division Sign-Off)

Division of Fladiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K 11 Z 4 S 1

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal				·				
	Abdominal	Р	Р	Р		P	Р	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic						<u> </u>		
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2
	Adult Cephalic	Р	Р	Р	Р	Ρ	Р	Note 1	Notes 2
	Trans-rectal						ì		
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular	1							
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	Ρ	Р	Р	Р	Р	Р	Note 1	Notes 2,3
	Cardiac Pediatric	Р	Р	Р	Р	P	Р	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	-							
Vessel	Other (specify)								

	1 (Conventional)	1	1	l					
	Musculo-skeletal]		
	(Superficial)	-							
	Intravascular				ŀ		1		
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	Р	Р	Р	Р	Note 1	Notes 2,3
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3
	Intravascular(Cardiac)					T			
	Trans-esoph.(Cardiac)								
	Intra-cardiac			1	Ì				
	Other (specify)		ĺ						
Peripheral	Peripheral vessel	٦.	İ						
/essel	Other (specify)						-		
Dopp Note 2: Tissue Note 3: TDI	Combined includes: B/M; B/ bler/PWD Harmonic Imaging. Note 4: 3D Organ: breast, thyroid, testes			ote 5: 4D		, Bredidi Be	pppier, b/Colo		B/T OWEI
Prescription Us (Part 21 CFR 8				AND/0)R			he-Counter Use _ 21 CFR 807 Subp	art C)
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Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

B10K K 112451

3-3

Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cl	inical Application					Mode	of Operation	· · · · · · · · · · · · · · · · · · ·	-
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic							•	
Fetal Imaging&	Fetal ·								
Other	Abdominal					<u> </u>			
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic		$ldsymbol{ldsymbol{ldsymbol{eta}}}$						
	Pediatric	P	Р	Р		Р	Р	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	Ρ	Р	P	P	Note 1	Notes 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	Р	Р	Þ	Р	Р	Р	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph (Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)								

	Cardiac Pediatric	Р	P	P	P	ļΡ	P	Note 1	Notes 2,3			
	Intravascular(Cardiac)											
	Trans-esoph (Cardiac)											
	Intra-cardiac											
	Other (specify)											
Peripheral	Peripheral vessel	I							1			
Vessel	Other (specify)											
N = new indication; P = previously cleared by FDA; E = added under this appendix												
Note 1: Other	Combined includes: B/M; B/P	WD:	B/T	HI; M/C	olor M;	B/Color Dop	pler; B/Color Do	oppler/PWD; B/	Power			
Dop	pler/PWD				·	•	,					
Note 2: Tissue Harmonic Imaging.												
Note 3: TDI	Note 4: 3D		No	te 5: 4D								
Note 6: Small	Organ: breast, thyroid, testes											
Prescription U	seX			AND/C)R			Counter Use				
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Indications For Use

3-4

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Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Ci	inical Application	Ī.				Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic -								
Fetal Imaging&	Fetal				•				
Other	Abdominal								
	Intra-operative Specify							•	
	Intra-operative Neuro					<u> </u>			
	Laparoscopic								
	Pediatric							-	
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
·	Trans-rectal	P	Р	Р		Р	Р	Note 1	Notes 2
	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2
	Trans-urethral					· ·	· · · · ·		
	Trans-esoph.(non-Card)								
•	Musculo-skeletal (Conventional)		·				·		
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)		Ī						
Cardiac	Cardiac Adult								
	Cardiac Pediatric						1		
	Intravascular(Cardiac)								ĺ
	Trans-esoph.(Cardiac)		i		1				
	Intra-cardiac								
	Other (specify)	1							
Peripheral	Peripheral vessel								
Vessel	Other (specify)								

	''an'o ocep'('oa'a'a'a'								1		
	Intra-cardiac										
	Other (specify)										
Peripheral	Peripheral vessel										
Vessel	Other (specify)										
N=new indication; P=previously cleared by FDA; E=added under this append Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD Note 2: Tissue Harmonic Imaging. Note 3: TDI Note 4: 3D Note 5: 4D Note 6: Small Organ: breast, thyroid, testes											
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Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application	Т	. Mode of Operation									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify			
Ophthalmic	Ophthalmic											
Fetal Imaging&	Fetal											
Other	Abdominal											
	Intra-operative Specify											
	Intra-operative Neuro											
	Laparoscopic											
	Pediatric											
	Small Organ (specify)											
	Neonatal Cephalic											
	Adult Cephalic	1										
	Trans-rectal	P	Р	Р		Р	Р	Note 1	Notes 2			
	Trans-vaginal	P	P	Р		P	Р	Note 1	Notes 2			
	Trans-urethral											
	Trans-esoph.(non-Card)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular				· · · · ·							
	Other (Ob/GYN)											
Cardiac	,Cardiac Adult											
	Cardiac Pediatric											
	·Intravascular(Cardiac)											
	Trans-esoph (Cardiac)											
	Intra-cardiac											
	Other (specify)											
Peripheral	Peripheral vessel								1			
Vessel	Other (specify)											

Cardiac	Cardiac Adult							
	Cardiac Pediatric		i					
	Intravascular(Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral	Peripheral vessel							
Vessel	Other (specify)							
Dopp Note 2: Tissue Note 3: TDI	Combined includes: B/M; B/P bler/PWD Harmonic Imaging. Note 4: 3D Organ: breast, thyroid, testes	·	THI; M/C	r	B/Color Do	ppler; B/Colo	or Doppler/PW	D; B/Power
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Indications For Use

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

3-6

Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal								
Other	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)		•						
	Neonatal Cephalic								
	Adult Cephalic						Î		
	Trans-rectal	P	Р	Р		P	Р	Note 1	Notes 2
	Trans-vaginal	P	Р	Р		P	Р	Note 1	Notes 2
	Trans-urethral	1							
	Trans-esoph.(non-Card)	1			 -		<u> </u>		
	Musculo-skeletal (Conventional)								
•	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)								

	Other (specify)										
Peripheral	Peripheral vessel										
Vessel	Other (specify)										
N = new indicatio	n; P = p	reviously o	lear	d by FDA	;		E = added under this appendix				
	Combined includes: B/M; bler/PWD	B/PWD;	B/1	THI; M/C	olor M ;	B/Color Dop	pler; B/Color D	oppler/PWD; E	3/Power		
Note 2: Tissue	Harmonic Imaging.										
Note 3: TDI	Note 4: 3D		N	ote 5: 4D							
Note 6: Small (Organ: breast, thyroid, tes	tes									
Prescription Us	seX			AND/C)R		Over-The-	Counter Use _			
(Part 21 CFR 8	01 Subpart D)						(21 CFR 807 Subpart C)				
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	Concurrence of CDRH	, Office	of Ir	Vitro D	iagnostic	Devices (OI	VD)	· · ·			
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Indications For Use

(D/ision Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application	Mode of Operation										
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify			
Ophthalmic	Ophthalmic											
Fetal Imaging&	Fetal											
Other	Abdominal	P	Р	Р	<u> </u>	Р	Р	Note 1	Notes 2			
	Intra-operative Specify											
	Intra-operative Neuro				L							
	Laparoscopic											
	Pediatric	Р	P	Р		P	P	Note 1	Notes 2			
	Small Organ (specify)											
	Neonatal Cephalic	P	Р	Р	P	P	Р	Note 1	Notes 2			
	Adult Cephalic	I										
	Trans-rectal	1										
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph.(non-Card)				i							
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)	<u> </u>										
	Intravascular	1										
	Other (Ob/GYN)	П										
Cardiac	Cardiac Adult											
	Cardiac Pediatric	P	Р	Ρ	P	P	Р	Note 1	Notes 2,3			
	Intravascular(Cardiac)	1	T									
	Trans-esoph.(Cardiac)											
	Intra-cardiac		l I									
	Other (specify)											
Peripheral	Peripheral vessel											
Vessel	Other (specify)				i							

	Other (specify)		,	i								
Peripheral	Peripheral vessel											
Vessel	Other (specify)			İ								
N = new indication; P = previously cleared by FDA; E = added under this appendix Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD Note 2: Tissue Harmonic Imaging.												
Note 3: TDI	Note 4: 3D gan: breast, thyroid, teste		Note 5: 4E)								
Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)												
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	Concurrence of CDRH (iffice of	In Vitro I	liannostic	Devices (OI)	ZDY						

Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application	Т				Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	P	Р	Р		Р	Р	Note 1	Notes 2,4
Other	Abdominal	P	Р	Р		P	Р	Note1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	1							
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	1							
	Trans-vaginal	1							-
	Trans-urethral	1							
	Trans-esoph.(non-Card)	i			İ				
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular		1						
	Other (Ob/GYN)	P	Р	Р		Р	Р	Note1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)	\top			1				
	Trans-esoph.(Cardiac)	1							
	Intra-cardiac								
	Other (specify)	1							
Peripheral	Peripheral vessel								
Vessel	Other (specify)	\top			•				

		1		L	1			3	
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)	Ī							
Dopp	a; P = previo Combined includes: B/M; B/F ler/PWD Harmonic Imaging.	•		d by FDA; HI; M/C		B/Color Dopp		= added under this oppler/PWD; B/	
Note 3: TDI	VV		No	ote 5: 4D					
Prescription Us (Part 21 CFR 86				AND/O	R			Counter Use CFR 807 Subpart	: C)
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	Concurrence of CDRH, O	ffice	of In	Vitro D	iagnostic	Devices (OIV	/D)		

Indications For Use

(Division Sign-Off) 3-9
Division of Radiotogical Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application	Mode of Operation										
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify			
Ophthalmic	Ophthalmic											
Fetal Imaging&	Fetal	Р	Р	Р		Р	Р	Note 1	Notes 2, 4			
Other	Abdominal	P	Р	Р		P	P	Note 1	Notes 2, 4			
	Intra-operative Specify	I										
	Intra-operative Neuro											
	Laparoscopic											
	Pediatric											
	Small Organ (specify)											
	Neonatal Cephalic					·			· · · · · · · · · · · · · · · · · · ·			
	Adult Cephalic	<u> </u>										
	Trans-rectal							·				
	Trans-vaginal							1				
	Trans-urethral											
	Trans-esoph.(non-Card)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular							<u> </u>				
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note 1	Notes 2, 4			
Cardiac	Cardiac Adult											
	Cardiac Pediatric					: -						
	Intravascular(Cardiac)					<u> </u>						
	Trans-esoph.(Cardiac)											
	Intra-cardiac					·						
	Other (specify)											
Peripheral	Peripheral vessel											
Vessel	Other (specify)											

	Intra-cardiac	l			J	1 .		1	<u> </u>
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)					İ	1		<u> </u>
N = new indication; Note 1: Other Co Dopple	mbined includes: B/M;	reviously o B/PWD;		-		B/Color Dop		= added under this oppler/PWD; B/	• •
Note 2: Tissue Ha						,			
Note 3: TDI	U U		No	ote 5: 4D					
Note 6: Small Org	gan: breast, thyroid, tes	stes							
Prescription Use (Part 21 CFR 801				AND/C	PR			Counter Use CFR 807 Subpart	(C)
(PLEASE	DO NOT WRITE BE	LOW TH	IS L	INE-CO	NTINUE	ON ANOTH	IER PAGE IF N	EEDED)	
	Concurrence of CDRI	I, Office	of In	Vitro D	iagnostic	Devices (OI	VD)		

Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Indications For Use

Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	ical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic			·		ĺ			
Fetal Imaging &	Fetal	Р	Р	Р		P	Р	Note 1	Notes 2,4,5
Other	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
	Intra-operative Specify					I	İ		
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)						·		
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal	1							
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)							:	
	Musculo-skeletal (Superficial)								
	Intravascular			l					
	Other (Ob/GYN)	Р	Р	Р		P	Р	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult								
	Cardiac Pediatric					Ĭ			
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	Ī							
	Intra-cardiac								
	Other (specify)					I			
Peripheral	Peripheral vessel								
Vessel	Other (specify)								

	Other (specify)		T		I .	i		I
Peripheral	Peripheral vessel							
Vessel	Other (specify)							
Doppler Note 2: Tissue Ha	mbined includes: B/M; B/I r/PWD	PWD; B/	red by FDA; THI; M/C	olor M ;	B/Color Dop		= added under oppler/PWD;	• • •
Note 6: Small Org	gan: breast, thyroid, testes							
Prescription Use (Part 21 CFR 801	X Subpart D)		AND/C	R			Counter Use FR 807 Subp	oart C)
(PLEASE	DO NOT WRITE BELOV	w THIS	LINE-CO	NTINUE	ON ANOTH	ER PAGE IF N	EEDED)	
	Concurrence of CDRH, C	ffice of l	n Vitro D	iagnostic	Devices (OI	VD) .		

Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal								
Other	Abdominal	<u> </u>	٠.						
	Intra-operative Specify					<u> </u>	. <u> </u>		
	Intra-operative Neuro						<u> </u>		
	Laparoscopic								
	Pediatric	<u> </u>							
	Small Organ (specify)	Р	Р	Р		P	P	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	1							
	Trans-vaginal							ì	
	Trans-urethral	1	T -						
	Trans-esoph.(non-Card)	1							
	Musculo-skeletal (Conventional)	Р	Р	Р		P	Р	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2, 4
	Intravascular								
	Other (Ob/GYN)					,			
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)	1							
	Trans-esoph.(Cardiac)								
	Intra-cardiac					L			
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	·P	Note 1	Notes 2, 4
Vessel	Other (specify)								

Peripheral	Peripheral vessel	Ρ	P	ļΡ		P	·P	Note 1	Notes 2,
Vessel	Other (specify)								
Doppl Note 2: Tissue I Note 3: TDI	r; P = previous; P = previous; P = previous; B/M; B/F ler/PWD Harmonic Imaging. Note 4: 3D Organ: breast, thyroid, testes	-	; B/T	d by FDA; HI; M/C ote 5: 4D		B/Color Dopp		= added under th pppler/PWD; E	
Prescription Use (Part 21 CFR 80				AND/O	R			Counter Use _ FR 807 Subpa	nt C)
(PLEAS	E DO NOT WRITE BELOW	TH	IS L	INE-CO	NTINUE	ON ANOTH	ER PAGE IF N	EEDED)	

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off) Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety 2

Indications For Use

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application				Mode of Operation										
Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify						
Ophthalmic														
Fetal														
Abdominal														
Intra-operative Specify														
Intra-operative Neuro								I						
Laparoscopic	Ι													
Pediatric														
Small Organ (specify)	Р	Р	P		P	Р	Note 1	Notes 2, 4						
			i											
Trans-rectal					ì									
Trans-vaginal	İ				 									
Trans-urethral	İ				Ì		i							
Trans-esoph (non-Card)		— —												
Musculo-skeletal (Conventional)	P	Р	Р		Р	Р	Note 1	Notes 2, 4						
Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2, 4						
Intravascular	i													
Other (Ob/GYN)														
Cardiac Adult														
Cardiac Pediatric]						
Intravascular(Cardiac)														
Trans-esoph.(Cardiac)		T												
Intra-cardiac				1				i						
Other (specify)														
Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2, 4						
Other (specify)	1				İ			1						
• • •	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Trans-esoph.(Cardiac) Intra-cardiac Other (specify) Peripheral vessel	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel P	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel P M M M M M M M M M M M M	Specific (TRACKS 1 & 3) Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Conventional) Intravascular Other (Ob/GYN) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel P P M PWD M PWD M PWD M PWD M PWD M PWD M PWD M PWD P P P P P P P P P P P P P	Specific (TRACKS 1 & 3) B M PWD CWD Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) P P P Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Cardiac Adult Cardiac Pediatric Intravascular(Cardiac) Intra-cardiac Other (specify) Peripheral vessel P P P	Specific (TRACKS 1 & 3) B M PWD CWD Doppler Ophthalmic Fetal Abdominal Intra-operative Specify Intra-operative Neuro Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Intravascular Other (Ob/GYN) Cardiac Adult Cardiac Pediatric Intrav-cardiac Other (specify) Peripheral vessel P P P P Color Doppler Color Doppler Color Doppler Color Doppler Color Doppler P P P P P P P P P P P P P P P P P P P	Specific (TRACKS 1 & 3) B M PWD CWD Doppler (Amplitude) Doppler	Specific (TRACKS 1 & 3)						

	Intravascular(Cardiac)		ļ						
	Trans-esoph.(Cardiac)		Ī						
	Intra-cardiac						1		
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		P	P	Note 1	Notes 2, 4
/essel	Other (specify)		<u> </u>						
N = new indication;	P = previo	usty o	leare	d by FDA	;			E = added under	this appendix
	mbined includes: B/M; B/P	WD;	B/T	'HI; M/C	color M;	B/Color De	oppler; B/Color	Doppler/PWD;	B/Power
Doppler	r/PWD								
Note 2: Tissue Ha	rmonic Imaging.								
Note 3: TDI	Note 4: 3D		No	ote 5: 4D)				
Note 6: Small Org	gan: breast, thyroid, testes								
Prescription Use	v			AND/C)D		Over-Th	ne-Counter Use	
(Part 21 CFR 801				ANDIC	, K			CFR 807 Subp	
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Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal								
Other	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro	1						ļ <u> </u>	
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	Р	₽		P	P	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	1							
	Trans-vaginal				† 				
	Trans-urethral								
	Trans-esoph.(non-Card)	1							
	Musculo-skeletal (Conventional)	P	Р	Р		Р	Р	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	P	Р	Р		Р	Р	Note 1	Notes 2, 4
	Intravascular								
	Other (Ob/GYN)						L		
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)	T	П						
	Trans-esoph.(Cardiac)		П						
	Intra-cardiac		1						
	Other (specify)	1							
Peripheral	Peripheral vessel	P	Р	Р		Р	Р	Note 1	Notes 2, 4
Vessel	Other (specify)				1				

	Intra-cardiac]	_					
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р	:	P	Р	Note 1	Notes 2, 4
Vessel	Other (specify)								
N = new indication	; P = previo	usly (leare	d by FDA;			E	= added under this	appendix
Doppl	ombined includes: B/M; B/P er/PWD	WD;	; B/I	HI, M/C	olor M ; l	B/Color Dopp	oler; B/Color Do	oppler/PWD; B/	Power
Note 2: Tissue I	larmonic Imaging.								
Note 3: TDI	Note 4: 3D		No	ote 5: 4D					
Note 6: Small O	organ: breast, thyroid, testes								
Prescription Use (Part 21 CFR 80				AND/O	R .			Counter Use FR 807 Subpart	C)
(PLEAS	E DO NOT WRITE BELOW	TH	IS L	INE-COI	NTINUE	ON ANOTH	ER PAGE IF N	EEDED)	
	Concurrence of CDRH, Of	fice	of lr	Vitro Di	iagnostic	Devices (OIV	/D)		,

Indications For Use

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